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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/889,430	01/17/2002	Mathieu Hubertus Maria Noteborn	2906-4992US	2965

7590 03/24/2003

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EXAMINER	
LI, QIAN J	

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 03/24/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/889,430	NOTEBORN ET AL.	
	Examiner	Art Unit	
	Q. Janice Li	1632	

-- *The MAILING DATE of this communication appears on the cover sheet with the correspondence address* --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 July 2001* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *17-36* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *17-36* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Election/Restrictions

1. This application contains the following inventions or groups of inventions, which are not so linked as to form a single inventive concept under PCT Rule 13.1. Restriction is required under 35 U.S.C. 121 and 372.

Group I. Claims 17, 18, 27, and 28, drawn to a method for treating an inflammatory disorder in a subject, comprising administering to the subject an apoptosis-inducing agent.

Group II. Claims 19-26, 31, and 33-36, drawn to a method for treating an inflammatory disorder in a subject, comprising administering to the subject a gene delivery vehicle comprising a gene capable of expressing an apoptosis-inducing agent.

Group III. Claims 29, 30, and 32, drawn to a method for determining the presence of autoimmune disease

2. The invention listed as groups I-III do not relate to a single inventive concept under PCT Rule 13.1, because under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Claims of group I differs from that of group II in that they are drawn to methods of using different products, such as a protein or a nucleic acid expressing a protein. The nucleic acid used in the method of group II is not required in the method of group I. The different methods use

different starting materials, which have different biodistribution and pharmacokinetics (different mode of operation), and thus, different methods require distinct technical considerations. Claims of group III differs from that of groups II and I in that they are drawn to an *in vitro* method for sample cell diagnosis. The method steps of group III do not require *in vivo* administration of a compound as used in the methods of groups II and I, for example. Since multiple processes are claimed, unity of invention is lacking and restriction is required. The differences in the special technical features of the Inventions I-III are further underscored by their divergent classification and independent search criteria.

Furthermore, as cited in the International Preliminary Examination Report, Group II, but not group I, is anticipated or obvious over the cited prior art of record (WO 98/37901). Consequently, the special technical feature of group II is not so linked with that of groups III and I, that they provide a contribution as a whole, makes over the prior art, so unity of invention is lacking. Applicants are advised to see 37 CFR 1.475 (a)-(d) for details.

Invention groups II and I may further comprise patentably distinct groups of inventions and/or patentably distinct species of inventions. This is because claim recitation, "an apoptosis inducing agent" encompasses numerous compounds that may be patentably distinct. For example, the cited prior art of record (WO 98/37901) anticipates an apoptosis inducing agent, TNFα, but not an apoptin, thus, the special technical feature of apoptin is not so linked with another apoptosis inducing agent such as TNF, and that they do not provide a contribution as a whole, makes over the prior art,

so unity of invention is lacking. Applicants are required to identify a particular apoptosis-inducing agent for examination in this application if one of the groups II or I is elected, and the election may be an election of an invention or a species election depending on the agents identified.

3. The invention group II further comprises patentably distinct species of inventions, i.e. different targeting means for the gene delivery vehicle. The means could be a targeting protein, such as a cell receptor ligand, or a nature tropism of a viral vector. Applicants are required to identify a particular targeting means as a species for examination if group II is elected.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 19-26, 31, 33-36 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

4. In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is advised that where a single claim encompasses more than one invention as defined above, upon election of an invention for examination, said claim will only be examined to the extent that it reads upon the elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Q. Janice Li whose telephone number is 703-308-7942. The examiner can normally be reached on 8:30 am - 5 p.m., Monday through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah J. Reynolds can be reached on 703-305-4051. The fax numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9307 for After Final communications.

Any inquiry of formal matters can be directed to the patent analyst, Dianiece Jacobs, whose telephone number is (703) 305-3388.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235. The faxing of such papers must conform to the notice published in the Official Gazette 1096 OG 30 (November 15, 1989).

Q. Janice Li
Examiner
Art Unit 1632

QJL
March 21, 2003